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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,574	08/05/2003	Ramin Shiekhattar	WSTR-0014C	1505

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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	PAPER NUMBER
1643	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/634,574	SHIEKHATTAR, RAMIN	
	Examiner	Art Unit	
	Anne L. Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-6 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 4/16/2007 is acknowledged. Clams 1-3, 7-12 and 14-17 were canceled.

2. Claims 4-6 and 13 are pending and examined on the merits.

Claim Rejections Withdrawn:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. The rejection of claims 4-6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claims

Claims 4-6 are indefinite in the recitation of BRCC, because at one point in the specification BRCC appears to be defined at page 5 of the specification as containing 10 elements, whereas at page 17, the specification appears to define BRCC as containing at least 2 elements from a list of proteins.

4. The rejection of claim 13 under 35 U.S.C. 102(b) as being anticipated by Li (Li, L. et al., Biochemical and Biophysical Research Communications, 206(2): 764-774, 1995) is withdrawn in view of the amendment limiting the agents to an agent selected from the group consisting of

an antisense molecule, a siRNA molecule, or a RNAi molecule or ribozymes targeted to nucleic acid sequences encoding BRCC36 or BRE.

5. The rejection of claim 13 under 35 U.S.C. 102(b) as being anticipated by Silverman (US 6,331,396; issue Dec. 18, 2001) is withdrawn in view of the amendment limiting the agents to an agent selected from the group consisting of an antisense molecule, a siRNA molecule, or a RNAi molecule or ribozymes targeted to nucleic acid sequences encoding BRCC36 or BRE.

6. The rejection of claim 4 under 35 U.S.C. 102(b) as being anticipated by Hashizume (Hashizume, R. et al., The Journal of Biological Chemistry, 276 (18): 14537-14540, 2001, May; cited in the IDS) is withdrawn in view of the amendment that BRCC is a multi-protein complex that consists of BRCA2, BRCA1, and RAD51, as well as one or more proteins selected from the group consisting of BARD1, BRCC300, BRCC140, BRCC130, BRCA1 Δ11, BRCC80, BRE, and BRCC36.

7. The rejection of claim 4 under 35 U.S.C. 102(a) as being anticipated by Mallery (Mallery, D.L. et al. The EMBO Journal, 21(24): 6755-6762, 2002, Dec.) is withdrawn in view of the amendment that BRCC is a multi-protein complex that consists of BRCA2, BRCA1, and RAD51, as well as one or more proteins selected from the group consisting of BARD1, BRCC300, BRCC140, BRCC130, BRCA1 Δ11, BRCC80, BRE, and BRCC36.

8. The rejection of claim 5 under 35 U.S.C. 102(b) as being anticipated by Preisler (Preisler, V.K. et al. Cancer Letters, 145: 29-33, 1999) as evidenced by Vissac (Vissac, C. et al. Clinical Chimica Acta, 320: 101-110, 2002) is withdrawn because Preisler does not appear to teach a method comprising the active step of monitoring the ability of an agent to alter cell survival rates in the presence of ionizing radiation or alter homology-directed DNA repair.

Claim Rejections Maintained and New Grounds of Rejection:

9. Claims 4-6 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. New grounds are presented.

The amendment filed 4/16/2007 appears to have introduced new matter into the specification as originally filed.

In claims 4-6, as currently amended, BRCC is defined as "a multi-protein complex that consists of BRCA2, BRCA1, and RAD51, as well as one or more proteins selected from the group consisting of BRAD1 (sic; BARD1), BRCC300, BRCC140, BRCC130, BRCA1 Δ11, BRCC80, BRE, and BRCC36". This appears to be a subgenus that was not originally contemplated. Applicants point to page 17 and to page 5 of the specification as providing support for the amendment. However, at page 17 of the specification, assays that contain BRCC are defined as assays that include two or more BRCC components from a list that of components that include but *are not limited to* BRCA2, BRCA1, RAD51, BRCC300, BRCC140, BRCC130,

BRCA1, BRCC80, BRE, BRCC36, and BARD1 (emphasis added). At page 5, BRCC is defined as a complex that contains BRCA2, BRCAI and RAD51 as well as BRCC300, BRCCI40, BRCCI30, BRCCI20, BRCC80, BRCC45 and BRCC36, which appears to be definition requiring all 10 components. At page 7 of the specification, a complex is described that contains BRCA1, BRCA2, BARD1 And RAD51. None of these teachings (page 17, page 5 or page 7) provides explicit or implicit support for the concept of a subgenus of BRCC complexes that consists of BRCA2, BRCA1, and RAD51, as well as one or more proteins selected from the group consisting of BARD1, BRCC300, BRCC140, BRCC130, BRCA1 Δ11, BRCC80, BRE, and BRCC36. While the subgenus currently recited in the claims is encompassed by the descriptions of BRCC provided by the specification, there does not appear to be any direction pointing to this particular subgenus in the specification as originally filed. Therefore, the amendment filed 4/16/2007 added new matter to the specification as originally filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Pradier (Pradier, O., et al, J. Cancer Res. Clin. Oncol. 125: 20-27, 1999) as evidenced by Chen (Chen, J.-J. et al, Cancer Research, suppl., 159: 1752s-1756s, 1999).

Applicants' arguments with respect to the previous rejection over Pradier as evidenced by Vissac have been carefully considered, but fail to persuade. In view of the amendment, limiting the term "BRCC" to a complex that consists of BRCA1, BRCA1, RAD51 as well as one or more proteins selected from the group consisting of BARD1, BRCC300, BRCC140, BRCC130, BRCA1 Δ11, BRCC80, BRE, and BRCC36, the rejection has been restated as anticipated by Pradier as evidenced by Chen. Applicants assert that Pradier does not measure DNA repair, but instead measures the survival of cells exposed to paclitaxel and radiation.

However, in response, applicants' attention is drawn to the fact that claim 5 comprises the active step of contacting a cell containing BRCC with a test agent and monitoring the ability of the agent to alter cell survival rates in the presence of ionizing radiation or alter homology-directed DNA repair which is indicative of DNA repair activity of BRCC. Pradier teaches this active step for MCF-7 cells (see page 25, Figure 4; page 21, 2nd column, 2nd paragraph). Chen provides evidence that MCF-7 cells contain a complex made up of BRCA1, BRCA2, RAD51 and BARD1 (see abstract; page 1752s, 2nd column, 2nd paragraph; page 1755s, 1st column, 2nd paragraph). Furthermore, it is noted that Dong (Dong, Y et al., Molecular Cell, 12: 1087-1099, 2003) teaches that BRCC (a complex described in the instant application) does not appear to be specific to the cells in which it was originally discovered (H1299 cells) (see page 1088, 2nd column). Therefore, it would appear that the presence of BRCC as defined on page 5 of the specification, where BRCC is defined as a complex that contains BRCA2, BRCA1 and RAD51 as well as BRCC300, BRCC140, BRCC130, BRCC120, BRCC80, BRCC45 and BRCC36, is present in all cells.

11. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Blagosklonny (Blagosklonny, M.V., et al. Cancer Res. 55(20): 4623-4626, 1995) as evidenced by Chen (Chen, J.-J. et al, Cancer Research (suppl., 159: 1752s-1756s, 1999) and also as evidenced by Saramaki (Saramaki, A. et al., Nucleic Acids Research, 34(2): 543-554, 2006).

Applicants' arguments with respect to the previous rejection over Blagosklonny in view of Vissac have been carefully considered, but fail to persuade. In view of the amendment, limiting the term "BRCC" to a complex that consists of BRCA1, BRCA1, RAD51 as well as one or more proteins selected from the group consisting of BARD1, BRCC300, BRCC140, BRCC130, BRCA1 Δ11, BRCC80, BRE, and BRCC36, the rejection has been restated as anticipated by Blagosklonny as evidenced by Chen.

The rejection is maintained because Blagosklonny teaches the active step of claim 6, which is that of contacting a cell containing BRCC with a test agent and monitoring the ability of the agent to alter the expression of genes containing p53 response elements.

Applicants assert that Blagosklonny does not teach or suggest a method of identifying agents that modulate the transcriptional regulator activity of a BRCC such as is defined in claim 6. However, Chen provides evidence that MCF-7 cells contain a complex made up of BRCA1, BRCA2, RAD51 and BARD1 (see abstract; page 1752s, 2nd column, 2nd paragraph; page 1755s, 1st column, 2nd paragraph), which is a BRCC that is encompassed by the claims. Furthermore, it is noted that Dong (Dong, Y et al., Molecular Cell, 12: 1087-1099, 2003) teaches that BRCC (a complex described in the instant application) does not appear to be specific to the cells in which it was originally discovered (H1299 cells) (se page 1088, 2nd column). Therefore, it would appear that the presence of BRCC as defined on page 5 of the specification, where BRCC is

defined as a complex that contains BRCA2, BRCA1 and RAD51 as well as BRCC300, BRCC140, BRCC130, BRCC120, BRCC80, BRCC45 and BRCC36, is present in all cells.

Conclusion

Claim 13 is free of the art and is allowable. Claims 4-6 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If

attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
June 26, 2007

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER